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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/474,478	12/29/1999	B. JACK LONGLEY	58434-A/JPW/	2296

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/474,478

Applicant(s)

LONGLEY, B. JACK

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-57 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 50-57 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The amendment received 3/8/04 has been entered and claims 50-57 are currently pending in this application.

In view of the arguments presented and amendments to the claims, the rejections of record under 35 USC 112, first paragraph, is hereby withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Columbo in view of Mohammadi.

What has been searched and considered here is:

A method of preventing or treating cutaneous inflammation by inhibiting a KIT protein.

Columbo (J of Immunology) entitled "The Human Recombinant c-kit Receptor Ligand, rhSCF, Induces Mediator Release From Human Cutaneous Mast Cells and Enhances IgE Dependent Mediator Release From Both Skin Mast Cells and Peripheral Blood Basophils" teaches in the abstract, a ligand for the c-kit proto oncogene receptor, a member of the tyrosine kinase receptor class, and the effects of c-kit receptor ligand stem cell factor on the release of inflammatory mediators from human skin mast cells.

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There were effects on mast cells related to human allergic reactions and SCF may modulate mast cells function under physiologic conditions. On page 604 column 1, antibodies which recognize human c-kit receptor is shown. On page 606 column 2 last paragraph bridging to 607, the antibodies against c-kit receptor and their effects were discussed.

The claims differ from Columbo in that they are directed to preventing or treating specifically where Columbo is measuring effects.

Mohammadi (Science) entitled "Structures of the Tyrosine Kinase Domain of Fibroblast Growth Factor Receptor in Complex with Inhibitors" teaches on page 955, protein tyrosine kinases are critical components of signaling pathways and selecting inhibitors have considerable therapeutic value.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to specifically treat with inhibitors as taught by Mohammadi in the method of Columbo because the inflammatory effects related to c-kit and that such effects are modifiable are taught by Columbo. Mohammadi is directed to inhibiting the same pathways as Columbo for therapeutic reasons. The connection between c-kit and cutaneous inflammation is clearly shown by Columbo. To select a known antibody such as ACK2 in view of Columbo who selects other antibodies would have been obvious because it would have the expected result.

Applicant's arguments filed 3/8/04 have been fully considered but they are not persuasive.

Applicant argues that Columbo describes in vitro experiments in contrast to the claimed method which is directed to in vivo methods. One cannot base in vivo methods on in vitro experiments because they are not completely predictable and are merely an incentive to experiment. Mohammadi does not teach a mast cell system.

It is the examiner's position that the in vitro experiments of Columbo are highly suggestive of inhibiting the stem cell factor signaling pathway to treat cutaneous inflammation which is why the study was performed. One routinely bases in vivo methods upon in vitro experiments which is why in vitro experiments are performed and one would have a high expectation of success in doing so. Mohammadi was cited to teach the therapeutic value of inhibiting tyrosine kinases for treating.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

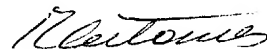
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner  
Art Unit 1651

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GROUP 1200